



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,818	12/18/2001	Brian Froehler	GLIS-0143	3496
32650	7590	12/08/2003	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE - 46TH FLOOR PHILADELPHIA, PA 19103			FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,818

Applicant(s)

FROEHLER ET AL.

Examiner

Jeffrey Fredman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 128-138 is/are pending in the application.
- 4a) Of the above claim(s) 128 and 131-134 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 129, 130 and 135-138 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 129, 130 and 135-138 in the paper filed October 7, 2003 is acknowledged.

Priority

This application claims priority from a particular attorney docket number 24610-20035.21, followed by a claim to application 07/935,444. The current application is not given priority to these applications since the intermediate application is not identified, except by attorney docket number, which is not in conformance with 37 CFR 1.78. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000,

Art Unit: 1634

after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Rejections - 35 USC § 102

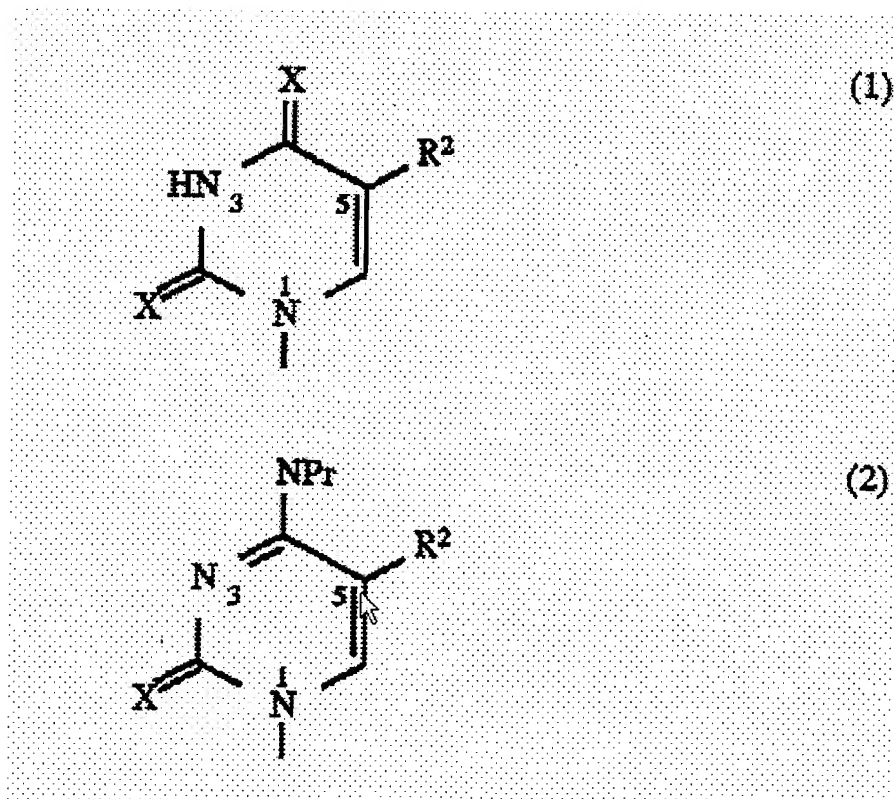
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

This rejection is applicable because the priority claim is denied above.

Froehler teaches “methods of detecting the presence, absence or amount of a particular single-stranded DNA or RNA or a particular target duplex in a biological (or other) sample using the oligomers of the invention, to detect selected nucleic acid sequences (see column 10, lines 39-45)” where the oligomers of the invention include bases of structures 1 and 2 below.

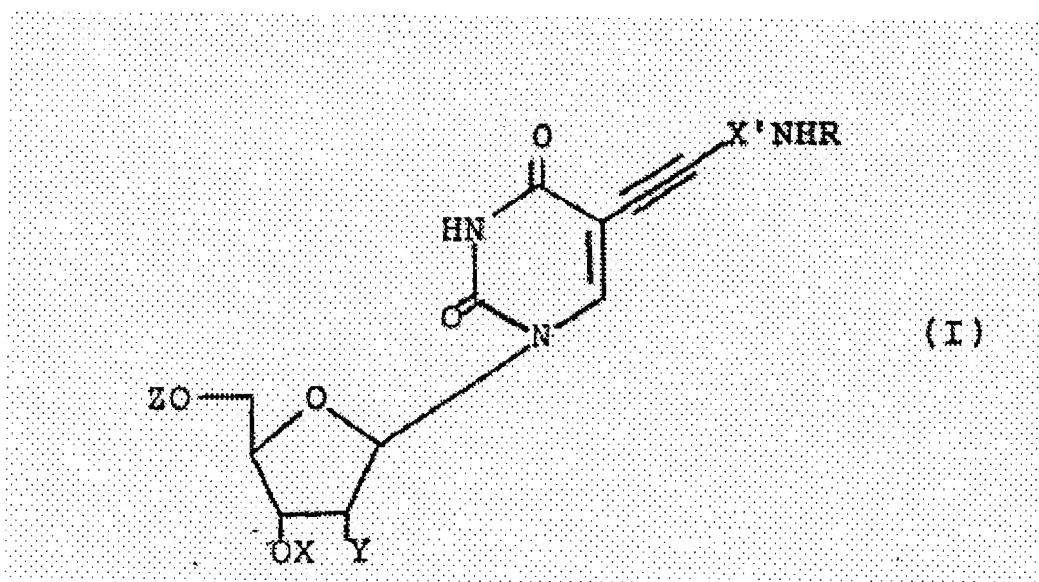


With regard to claims 135-138, Froehler further teaches "Oligomers of the invention containing 5-modified pyrimidines are compatible with polymerases used in polymerase chain reaction methods such as the Tag or Vent.TM. polymerase (see column 35, lines 26-29)."

4. Claims 129 and 130 are rejected under 35 U.S.C. 102(b) as being anticipated by Haralambidis et al (WO 88/10264).

Haralambidis teaches a method of detecting the presence of a single stranded DNA or RNA (see abstract,) comprising;

(a) selecting an oligomer having at least one base of formula (I)



where X is an oxygen and

where R^2 comprises the triple bonded pi group, (see specification, which defines a Pi bond "as used herein means an unsaturated covalent bond such as a double or triple bond."

Haralambidis expressly teaches that nucleic acids comprising the compound may be used in hybridization detection methods (see page 17, lines 9-15) as well as in DNA sequencing reactions (see page 17, line 16 to page 18, line 33).

Haralambidis further teaches, in example 9, hybridization of the labeled probe comprising the base given above to quantitative amounts of RNA dot blots (see page 39) to detect the presence and amount of specific mRNAs (see page 32 and figure 6).

With regard to claim 130, Haralambidis teaches quantitation of mRNA of kallikrein (see figure 6 and example 9).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

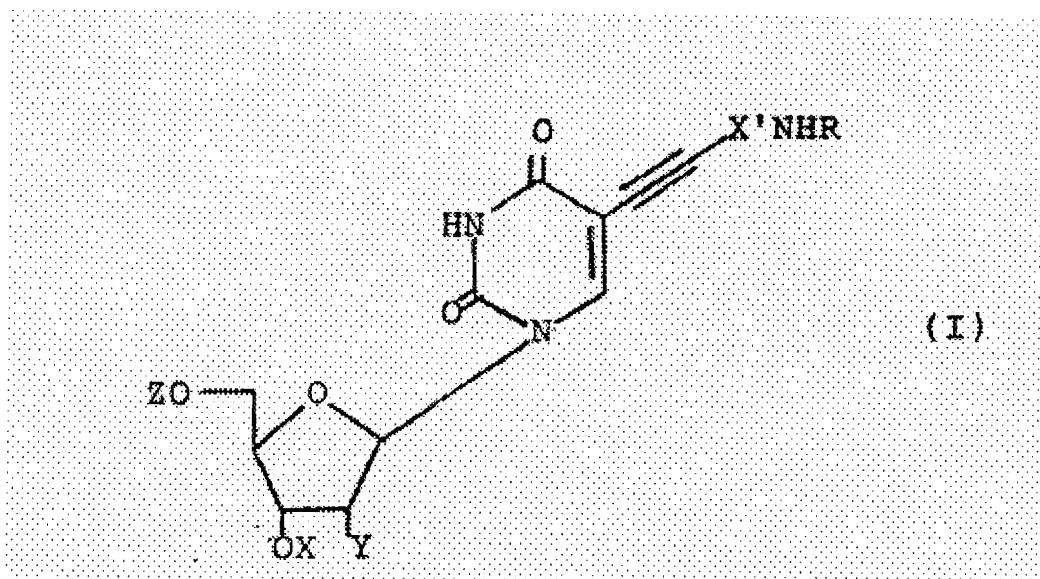
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 135-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambidis et al (WO 88/10264) as applied to claims 129 and 130 and further in view of Gelfand et al (U.S. Patent 5,079,352)

Haralambidis teaches a method of detecting the presence of a single stranded DNA or RNA (see abstract,) comprising;

(a) selecting an oligomer having at least one base of formula (I)



where X is an oxygen and

where R^2 comprises the triple bonded pi group, (see specification, which defines a Pi bond "as used herein means an unsaturated covalent bond such as a double or triple bond."

Haralambidis expressly teaches that nucleic acids comprising the compound may be used in hybridization detection methods (see page 17, lines 9-15) as well as in DNA sequencing reactions (see page 17, line 16 to page 18, line 33).

Haralambidis further teaches, in example 9, hybridization of the labeled probe comprising the base given above to quantitative amounts of RNA dot blots (see page 39) to detect the presence and amount of specific mRNAs (see page 32 and figure 6).

With regard to claim 130, Haralambidis teaches quantitation of mRNA of kallikrein (see figure 6 and example 9).

Haralambidis teaches the use of the polynucleotide comprising compound (I) above for use in nucleic acid extension reactions with a DNA polymerase (see page 15, lines 1-10), but Haralambidis does not teach the use of PCR.

Gelfand teaches PCR (see column 6) using the Taq polymerase (see column 7, lines 48-65).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the polynucleotide of Haralambidis with the PCR of Gelfand since Gelfand states "Amplification is particularly useful if such an analysis is to be done on a small sample using non-radioactive detection techniques which may be inherently insensitive or where radioactive techniques are being employed but where rapid detection is desirable (column 26, lines 47-52). Gelfand also states "The present invention may be useful not only for producing large amounts of an existing nucleic acid of completely specified sequence, but also for producing nucleic acid sequences which are known to exist but are not completely specified (column 16, lines 64-68)". An ordinary practitioner would have been motivated to combine the

Art Unit: 1634

teachings of Haralambidis and Mullis for the stated and expected benefits of increasing the amounts of nucleic acid, greater sensitivity and rapid detection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is currently 703-308-6568. In mid January, 2004, when TC 1600 relocates to the new USPTO facility in Alexandria, the examiner's phone number will become 571-272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The supervisor's new telephone number in mid January will be 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is currently 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1634